#### **GYNECOLOGY**

# A critical assessment of morcellation and its impact on gynecologic surgery and the limitations of the existing literature

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he role of power morcellation in gynecologic surgery recently has come under intense scrutiny after a highly publicized case of dissemination of unexpected uterine leiomyosarcoma. Morcellators were introduced initially in 1973 as a hand-activated device for laparoscopic tissue removal. The first electromechanical morcellator was made available by Steiner in 1993. As minimally invasive surgical techniques evolved, morcellation became a mainstay of gynecologic surgery. However, the risk of spreading malignant tissues must be balanced deliberately with the benefits of minimally invasive surgery. The purpose of this review was to provide an overview of the current literature in incidental uterine sarcomas, the accuracy of clinical and radiologic predictors of uterine malignancy, and a brief review of the impact of morcellation and future guidelines on the use of mechanical morcellators in gynecologic surgery.

### Incidence of sarcoma unsuspected at hysterectomy

Uterine sarcomas are rare, comprising <1% of all gynecologic malignancies.<sup>2</sup> This subgroup of uterine malignancies carries a poor prognosis for those affected, even in early-stage disease (Table 1).3-7 In the United States, of the estimated 52,630 new cases of uterine cancer diagnosed annually, approximately Uterine sarcomas are rare uterine malignancies that are difficult to diagnose preoperatively. Because of cases of disseminated sarcoma after laparoscopic hysterectomy, the role of power morcellators in gynecologic surgery has been questioned. Morcellation is an integral part of making laparoscopic surgery possible for the removal of large uterine leiomyomata, and the development of power morcellation has increased efficiency during these procedures. Minimally invasive surgery has demonstrated benefits that include improved pain control, decreased infection risk, and faster surgical recovery and return to work. In this review, we examine the risk of incidental sarcoma at the time of surgery, the quality of the data, the accuracy of clinical and radiologic predictors of uterine sarcoma, and the impact of morcellation on the prognosis of uterine sarcoma.

Key words: minimally invasive surgery, morcellation, uterine sarcoma

1600 will be uterine sarcomas. The major challenge with triaging patients to the appropriate surgery is differentiating uterine sarcomas from benign uterine fibroid tumors. Using various imaging techniques, endometrial sampling, obtaining a detailed patient history, and performing a thorough physical examination have been the mainstay of preoperative evaluation for patients with uterine masses. Although these techniques provide adequate evaluation for uterine epithelial cancers, each has limitations and none can exclude the possibility of nonepithelial malignancies.

There are varying reports in the literature on the incidence of unsuspected uterine sarcoma diagnosed on final pathologic evaluation after hysterectomy. Additionally, these studies are retrospective, which further limits the quality of the data. In the special report on power morcellation and occult malignancy in gynecologic surgery issued by the American Congress of Obstetrics and Gynecology (ACOG), it is estimated that 1 in 500 women will have a postoperative diagnosis of stromal sarcoma and leiomyosarcoma.9 As part of the safety warning issued by the US Food and Drug Administration (FDA) on power morcellation, a comprehensive literature review of studies that reported unsuspected uterine sarcomas and leiomyosarcomas in patients who underwent hysterectomy or myomectomy for presumed benign fibroid tumors was performed. Among this population, the risks of occult sarcoma and leiomyosarcoma were reported to be 1 in 352 and 1 in 458, respectively. 10

#### Quality of the data

Further review of the studies used for the FDA's report confirms low-quality evidence from retrospective reviews. Moreover, many of the studies were done at large referral centers on highrisk patients, possibly falsely elevating the risk of uterine sarcomas in these

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/ariable	Year published	Stage	n	Survival outcome
Leiomyosarcoma				_
Kapp et al <sup>3</sup>	2008	I	951	5-yr DSS = 75.8%
		II	43	5-yr DSS = 60.1%
Abeler et al <sup>4</sup>	2009	I	193	5-yr OS = 51%
		II	36	5-yr 0S = 25%
Endometrial stromal sarcoma				
Chan et al <sup>5</sup>	2008	I-II	540	6-yr DSS = 89%
Abeler et al <sup>4</sup>	2009	I	56	5-yr OS = 84%
		II	21	5-yr 0S = 62%
Adenosarcoma		•••••••••••••••••••••••••••••••••••••••		
Arend et al <sup>6</sup>	2010	l	327	5-yr 0S = 79%
Undifferentiated uterine sarcoma				
Abeler et al <sup>4</sup>	2009	<u> </u>	14	5-yr 0S = 57%
		II	5	5-yr 0S = 0%
Tanner et al <sup>7</sup>	2012		7	Median $OS = 26.8 \text{ m}$

study groups. Of the 9 studies that were included in the FDA quantitative assessment, 5 studies were conducted in the United States (Table 2). 11-15 All the studies were qualitative in nature, providing level 3 evidence<sup>16</sup> on the risk of uterine sarcoma at the time of hysterectomy. The largest study included 1429 patients who were 36-62 years old with abnormal uterine bleeding or abdominal pain with a pelvic mass of sufficient size or character to warrant

surgical exploration. In that study, they reported 7 cases of leiomyosarcoma (0.5%). Review of the study criteria shows that there was no standard preoperative evaluation among these patients who were treated between 1983 and 1988. The study was based out of a tertiary care center with a self-referred indigent population. Two additional US studies that were reviewed by the FDA report rates of uterine sarcoma of 0.18-0.23% and leiomyosarcoma of 0.08-0.09% in high-risk patients with inconsistent preoperative work-up. 12,14 Notably, of the studies that were reviewed by the FDA, multiple surgical and morcellation techniques were used to treat these patients.

Variable preoperative evaluation and lack of age and risk factor stratification among these retrospective studies ultimately lend uncertain relevance to these published data. With an annual reported incidence of 0.64 per 100,000 women, the applicability is further complicated by the rarity of these malignancies.<sup>17</sup> There are limited data on the prevalence of sarcoma in morcellated specimens and even fewer cases and studies on the incidence of disseminated disease in patients who underwent minimally invasive surgical techniques with the use of power morcellation. 14,18-22 To fully evaluate the effect of power morcellation on disease-free and overall survival in these cases, prospective studies or randomized studies are necessary; however, no such study is possible due to obvious ethical conflicts. Furthermore, the rarity of these cancers requires that data be collected over a long period of time to accrue the necessary numbers to provide sufficient statistical power to detect differences in outcome. Use of epidemiologic modeling systems may be needed to better understand the impact of morcellation in these cases. Without reliable data, any recommendation on the safety of power morcellation is premature, given the known benefits of minimally invasive surgery on patient recovery and quality of life.

Author	Year published	Procedure	n	Cases of sarcomas, n	Risk of uterine sarcoma, % (95% confidence interval)	Level of evidence
Leibsohn et al <sup>11</sup>	1990	Hysterectomy	1429	7	0.5 (0.1-0.9)	3
Parker et al <sup>12</sup>	1994	Hysterectomy or myomectomy	1332	4	0.2 (0.0—0.5)	3
Rowland et al <sup>13</sup>	2011	Hysterectomy	1115	8	0.5 (0.1-0.8)	3
Seidman et al <sup>14</sup>	2012	Myomectomy	1091	2	0.2 (0.0-0.4)	3
Ehdaivand et al <sup>15</sup>	2014	Hysterectomy	352	3	0.8 (0.2—2.5)	3
TOTAL			5319	24	0.5 (0.1-0.7)	

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